

Serial No.: 10/502,290
Group Art Unit No.: 1651

Amendment to the Claims:

1. (Currently amended): A DNA pharmaceutical agent dosage form, comprising having a dense core element coated with a solid reservoir medium containing the DNA pharmaceutical agent, further comprising a stabilising agent that inhibits the degradative effects of free radicals.

2. (Canceled):

3. (Currently amended): ~~A~~ The DNA pharmaceutical agent dosage form as claimed in claim 2 1 wherein the stabilising agent is one or both of a metal ion chelator and a free radical scavenger.

4. (Currently amended): ~~A~~ The A DNA pharmaceutical agent dosage form as claimed in claim 3 wherein the metal ion chelator is selected from the group consisting of: inositol hexaphosphate; tripolyphosphate; succinic and malic acid; ethylenediamine tetraacetic acid (EDTA); tris (hydroxymethyl) amino methane (TRIS); Desferal; diethylenetriaminepentaacetic acid (DTPA); and ethylenediamindihydroxyphenylacetic acid (EDDHA).

5. (Currently amended): ~~A~~ The DNA pharmaceutical agent dosage form as claimed in claim 3 wherein the free radical scavenger is selected from the group consisting of ethanol, methionine and glutathione.

6. (Currently amended): ~~A~~ The DNA pharmaceutical agent dosage form as claimed in claim 1 wherein the stabilising agent that inhibits the degradative effects of free radicals, is a member selected from the group consisting of: Phosphate buffered ethanol solution in combination with methionine or EDTA; and Tris buffered EDTA in combination with methionine or ethanol or a combination of methionine and ethanol.

7. (Currently amended): ~~A~~ The DNA pharmaceutical agent dosage form as claimed in claim 1, wherein the solid reservoir medium is an amorphous polyol.

8. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 7, wherein the polyol is a stabilizing polyol.

9. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 1 wherein the solid biodegradable reservoir medium is a sugar.

10. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 9 wherein the sugar is a member selected from the group consisting of lactose, glucose, sucrose, raffinose and trehalose.

11. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 1 wherein the solid reservoir medium is in the form of a glass.

12. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 11, wherein the solid reservoir medium is in the form of a sugar glass.

13. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 1, wherein the DNA pharmaceutical agent is supercoiled plasmid DNA.

14. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 13, wherein the supercoiled plasmid DNA is stabilized such that after storage at 37°C for 4 weeks greater than 50% of the DNA remains in its supercoiled form.

15. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 13, wherein the DNA is stabilized such that when released the ratio of monomer:dimer supercoiled form is within the range of 0.8:1.2.

16. (Currently amended): A The DNA pharmaceutical agent dosage form as claimed in claim 1, wherein the DNA pharmaceutical agent is a vaccine.

Serial No.: 10/502,290
Group Art Unit No.: 1651

17. (Currently amended): ~~A~~ The DNA pharmaceutical agent dosage form as claimed in claim 1, wherein the solid reservoir medium further comprises a member selected from the group consisting of vaccine adjuvant, transfection facilitating agent, DNAase inhibitor and a crystal poisoner.

18. (Currently amended): ~~A~~ The DNA pharmaceutical agent dosage form as claimed in claim 17, wherein the vaccine adjuvant is a member selected from the group consisting of CpG, a synthetic imidazoquinoline, tucerasol, a cytokine, MPL, QS21, QS7 and an oil in water emulsion.

19. (Currently amended): ~~A~~ The DNA pharmaceutical agent dosage form, as claimed in claim 1 wherein the dense core element comprises microbeads of a mean particle diameter of between 0.5 to 10 μm .

20. (Currently amended): ~~A~~ The DNA pharmaceutical agent dosage form as claimed in claim 19, wherein the microbeads are gold or tungsten microbeads.

21. (Withdrawn): A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 1, comprising making a solution of DNA pharmaceutical agent, reservoir medium, and stabilising agent that inhibits the degradative effects of free radicals in an solvent, followed by coating the at least one dense core element with said solution, and removing the solvent to form a solid reservoir medium containing the pharmaceutical agent and agent that inhibits the degradative effects of free radicals.

22. (Withdrawn): A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 21, wherein the reservoir medium is a sugar.

23. (Withdrawn): A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 22 wherein the concentration of sugar prior to removing the solvent is in the range of 20-40% w/v.

Serial No.: 10/502,290
Group Art Unit No.: 1651

24. (Withdrawn): A process for the preparation of a DNA pharmaceutical agent dosage form as claimed in claim 23, wherein the solvent is demetalated prior to the process.